PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Jussi NURMI et al.

Serial Number: 10/579,137 Group Art Unit: 1637

Filed: May 15, 2006 Examiner: Mummert, Stephanie K.

For: NUCLEIC ACID AMPLIFICATION ASSAY AND ARRANGEMENT THEREFOR

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 September 10, 2008

Sir:

In response to the Restriction Requirement mailed July 11, 2008, a Petition for a one month Extension of Time being submitted herewith, Applicants provisionally elect Group I, claims 1-13, with traverse.

The restriction requirement should be withdrawn because Group I, claims 1-13 are patentably distinct from WO 02/04921 to Burshteyn et al. The claimed method is a nucleic acid amplification assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample. Nucleic acid amplification assays require an enzymatic or chemical nucleic acid amplification step which employs a catalytic moiety such as an enzyme capable of amplifying a nucleic acid (Specification, page 6, lines 11-13).

Burshteyn et al. fails to disclose or suggest the nucleic acid amplification step of the claimed method. Instead, Burshteyn et al. discloses a method for using a filtration device to remove interferants from a sample containing cells in an automated apparatus. There is no mention of assays which include an enzymatic or chemical amplification of an analyte. Instead, Burshteyn et al. is directed to binding assays in which a labeled probe, such as an antibody, non-antibody or nucleic acid probe, binds to a target molecule and the binding is analyzed directly using, e.g., flow cytometry. See Example 3 of Burshteyn et al. Importantly, the binding of a probe to its target does not involve catalysis - no chemical reaction other than the binding reaction occurs.

Example 8, entitled "Other Applications," suggests the Burshteyn et al. method can be applied to many assays, and mentions that DNA and RNA probes are "expected" to be compatible with the invention. However, one of ordinary skill in the art would understand that DNA and RNA probes are compatible with a vast group of assays, of which nucleic acid amplification assays would only form a very specific group with highly specific features.

One of ordinary skill in the art would not have a reasonable expectation of success that the Burshteyn et al. method could be modified or applied to nucleic acid amplification assays. Such assays always include a catalytic step, typically catalyzed by enzymes. Yet enzymatically-catalyzed reactions are often plagued by inhibitors present in many different sample matrices. Substances which can inhibit a typical nucleic acid amplification reaction include different proteins, lipids and small molecules, which are abundant in many biological and non-biological sample matrices.

One of ordinary skill in the art would not expect interfering substances which can normally inhibit an enzymatic nucleic acid amplification reaction from occurring to inhibit the binding reaction between a labeled probe and its target. However, those skilled in the art would expect uninhibited catalysis by an enzyme in a nucleic acid amplification assay to require a more thorough purification of the nucleic acids present in a sample than what is disclosed by Burshteyn et al.

Reconsideration and withdrawal of the restriction requirement and examination of the entire application, are earnestly requested.

A Petition and fee for a one month Extension of Time are attached. It is not believed any additional fee is required for entry and consideration of this Response. Nevertheless, the Commissioner is authorized to charge Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,

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Enclosure:
Petition for Extension of Time